

UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEW HAMPSHIRE

Marine Polymer Technologies, Inc.

v.

Civil No. 06-cv-100-JD
Opinion No. 2009 DNH 031

HemCon, Inc.

O R D E R

Following their motions for summary judgment, Marine Polymer Technologies, Inc. and HemCon, Inc. filed motions to strike all or part of witness declarations filed by the opposing party. The motions are resolved as follows.

I. HemCon's Motions to Strike the Declarations of Robert S.
Langer

Marine Polymer filed the declaration of its expert witness, Robert S. Langer, Ph.D., in support of its motion for partial summary judgment on literal infringement. It also filed a declaration by Langer in support of its opposition to HemCon's motion for summary judgment. HemCon moves to strike both declarations, or parts of them, on the grounds that they are not based on Langer's personal knowledge, as required by Federal Rule of Civil Procedure 56(e), that the opinions are not reliable, and that the opinions offer impermissible legal conclusions.

A. Rule 56(e)

Rule 56(e) requires that “[a] supporting or opposing affidavit [] be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant is competent to testify on the matters stated.” Fed. R. Civ. P. 56(e)(1). In the context of an affidavit offering the opinion of an expert witness submitted in support of or in opposition to a motion for summary judgment, the expert’s opinions, stated in an affidavit, are subject to Rule 56(e) and Federal Rules of Evidence governing expert testimony. Poulis-Minott v. Smith, 388 F.3d 354, 360 (1st Cir. 2004); James Wm. Moore, Moore’s Federal Practice § 56.14[1][e][I], 56-199 (3d ed. 2008). Under Rule 703, therefore, expert witnesses can present opinions in affidavits, submitted in support of or in opposition to summary judgment, that are not based on their personal knowledge. United States v. Dailide, 227 F.3d 385, 392 (6th Cir. 2000).

An expert’s affidavit must explain the factual basis and methodology used to arrive at the opinion, although the affidavit need not include all of the facts and data relied on in forming the opinion. Moore’s § 56.14[1][e][I] & [ii]. An expert who provides an affidavit with an opinion formed within his area of expertise and based on his own assessment or analysis of the underlying facts or data satisfies the personal knowledge

requirement of Rule 56(e). See Doe v. Cutter Biological, Inc., 971 F.2d 375, 385-86 n.10 (9th Cir. 1992); Colgan v. Fisher Scientific Co., 935 F.2d 1407, 1423 & n.15 (3d Cir. 1991); Monks v. Gen. Elec. Co., 919 F.2d 1189, 1192 (6th Cir. 1990). An expert's conclusory opinions, set forth in an affidavit, do not meet the requirements of Rule 56(e). Novartis Corp. v. Ben Venue Labs., Inc., 271 F.3d 1043, 1051 (Fed. Cir. 2001).

1. Expert Affidavit Submitted for Summary Judgment

To the extent HemCon contends that an expert's affidavit must state that it is based on his personal knowledge, that theory is unsupported. In addition, expert opinion is not excluded per se from consideration for purposes of summary judgment as HemCon urges.¹ Instead, expert opinions in the form

¹HemCon relies on Shearing v. Iolab Corp., 712 F. Supp. 1446, 1454 (D. Nev. 1989), to support its theory that expert opinion cannot be presented in an affidavit or declaration for purposes of summary judgment. That part of the Shearing decision, which suggests that expert opinion cannot be used at the summary judgment stage, is incorrect. See McElyea v. Navistart Int'l Transp. Corp., 788 F. Supp. 1366, 1374 (E.D. Pa. 1991) (explaining Shearing court's error). HemCon also asserts that this court held in Insight Techs. Inc. v. SureFire, LLC, 2005 DNH 112 (Aug. 2, 2005), that expert opinion was not admissible for purposes of summary judgment. HemCon is mistaken. Instead, consonant with the standard stated above, the court noted that conclusory statements of infringement in an affidavit were insufficient to support summary judgment. Id.

of affidavits and declarations that satisfy the standard stated above are competent evidence to be considered for purposes of summary judgment.

2. Sufficiency of Declaration Submitted in Support of Summary Judgment

HemCon contends that Dr. Langer's opinions are not based on his personal knowledge because he conducted no tests himself and instead relied on test results and statements produced by HemCon. In response, Marine Polymer points out that an expert need not conduct his own testing as long as the opinions expressed are based on the expert's own work and that the materials analyzed to form the opinions are those reasonably relied on by experts in the field. Marine Polymer states that the information and materials Dr. Langer relied on to form his opinions are of the type that experts in the field use.

"[A]n expert need not have obtained the basis for his opinion from personal perception." Monsanto Co. v. David, 516 F.3d 1009, 1015 (Fed. Cir. 2008). Personal perception is also not necessary as the basis for an expert's opinion affidavit submitted for purposes of summary judgment. Dailide, 227 F.3d at 392. If scientific test results prepared by others are the type of information that experts in the field reasonably rely on, it

may form the basis of an expert's opinion, including an opinion provided in an affidavit for purposes of summary judgment. See Boim v. Holy Land Found. for Relief & Dev., 549 F.3d 685, 704-05 (7th Cir. 2008); Monsanto, 516 F.3d at 1015 (citing Fed. R. Civ. P. 703).

Although HemCon faults Dr. Langer for failing to conduct his own testing, HemCon has not shown that experts in the field do not rely on tests conducted by others. Therefore, based on the record presented, Dr. Langer's opinion in his declaration, based on the stated materials and test results, meets the requirements of Federal Rule of Civil Procedure 56(e).

3. Sufficiency of Declaration Submitted in Opposition to Summary Judgment

HemCon also contends that Dr. Langer's declaration submitted in support of Marine Polymer's opposition to HemCon's motion for summary judgment is not based on his personal knowledge. HemCon faults the opinions in the declaration for being based on Dr. Langer's review of documents provided to him for purposes of this litigation. HemCon argues that Dr. Langer's opinions do not meet the personal knowledge requirement of Rule 56(e).²

²In support, HemCon relies on Kern v. Tri-State Ins. Co., 386 F.2d 754, 756 (8th Cir. 1967), where the trial court rejected

Marine Polymer points to the stated factual bases for Dr. Langer's opinions and, again, asserts that the materials and information Dr. Langer used to form his opinions meet the requirements of Rule 703. HemCon does not dispute that the bases for Dr. Langer's opinions satisfy Rule 703. Instead, as above, HemCon argues that for purposes of summary judgment, expert opinions must be based on facts that the expert personally observed. As is discussed above, the premise of HemCon's theory is wrong. Therefore, HemCon has not shown that Dr. Langer's opinions fail to satisfy Rule 56(e).

B. Reliability of Dr. Langer's Opinions

HemCon contends that Dr. Langer's opinion that HemCon's accused bandage has no detectable biological reactivity as determined by biocompatibility tests and that the bandage exhibits high purity are not reliable. HemCon challenges those

a physician's opinion affidavit that the plaintiff was mentally incompetent because the opinion was based on letters from other doctors and summaries of hospital records rather than examination of the plaintiff, himself. The appellate court affirmed the trial court's discretionary decision to reject the affidavit and also noted that the opinion was not based on personal knowledge of the physician. Id. In doing so, the court appears to have concluded that physicians would not reasonably form an opinion about a person's mental competence without examining the person. Particularly in light of more recent analysis of the issue, Kern does not establish a requirement of personal knowledge based on the expert's own examination or testing of the subject.

opinions on the ground that they do not meet the requirements of Federal Rule of Evidence 702. In particular, HemCon challenges Dr. Langer's methods used in forming his opinions, asserting that he improperly relied on testing done by others that was documented in materials produced in discovery and that he failed to consider contrary test results.

Marine Polymer contends that HemCon's challenge to the reliability of Dr. Langer's opinions is untimely. Pursuant to the scheduling order in this case, issued on June 28, 2006, all challenges to expert testimony were to be filed on or before August 3, 2007. HemCon's motions to strike were filed on September 22 and October 20, 2008, well after the deadline for challenging expert opinions had passed.

Although a scheduling order may be modified based on a showing of good cause, HemCon has not requested such relief. Fed. R. Civ. P. 16(b)(4); Trans-Spec Truck Serv., Inc. v. Caterpillar Inc., 524 F.3d 315, 327 (1st Cir. 2008). In fact, HemCon has not addressed the timeliness issue at all. "Parties have an obligation to object to an expert's testimony in a timely fashion." Feliciano-Hill v. Principi, 439 F.3d 18, 24 (1st Cir. 2006). An untimely challenge to an expert's opinion may be rejected. Id.

HemCon's challenge, being untimely, is rejected. In addition, HemCon's attack on the reliability of Dr. Langer's opinions does not provide a basis for excluding the opinions. HemCon, as noted above, faults Dr. Langer for relying on test results produced by others. If, as Marine Polymer asserts without contradiction, experts in the field of determining biocompatibility and effectiveness of the products at issue in this case would rely on testing done by others, then Dr. Langer's opinions are properly based on that information. See Crowe v. Marchand, 506 F.3d 13, 17-18 (1st Cir. 2007). To the extent HemCon disagrees with Dr. Langer's analysis of the tests or believes that other pertinent information exists that was not considered by Dr. Langer in forming his opinions, those matters are appropriately raised to undermine the weight given Dr. Langer's opinions.

C. Legal Opinions

HemCon asserts that Dr. Langer's opinions "are merely legal conclusions." In particular, HemCon contends that patent invalidity is a determination to be made by the court, making opinion testimony inappropriate on that issue. HemCon also criticizes Dr. Langer's opinions related to patent invalidity on

other grounds, arguing that his analysis is contradictory and wrong.

HemCon contends that the patent at issue in this case, United States Patent No. 6,864,245, is invalid due to obviousness and anticipation. "Obviousness under 35 U.S.C. § 103 is a question of law, with underlying factual considerations regarding (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed invention, (3) the level of ordinary skill in the art, and (4) any relevant secondary considerations." Ball Aerosol & Specialty Container, Inc. v. Limited Brands, Inc., 555 F.3d 984, 991 (Fed. Cir. 2009). "Anticipation is a question of fact" based on determinations "that every element and limitation of the claim was previously described in a single prior art reference, . . . so as to place a person of ordinary skill in possession of the invention," and "the description must be such that a person of ordinary skill in the field of the invention can practice the subject matter based on the reference, without undue experimentation." Sanofi-Sythelabo v. Apotex, Inc., 550 F.3d 1075, 1082 (Fed. Cir. 2008). Expert witness testimony is commonly used for purposes of proving and opposing claims of patent invalidity. See, e.g., KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1745 (2007) (directing that when a district court is considering summary judgment on the

issue of obviousness, the “court can and should take into account expert testimony, which may resolve or keep open certain questions of fact”); Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1361 (Fed. Cir. 2008); Sanofi-Sythelabo, 550 F.3d at 1083.

To the extent HemCon contends that expert opinions are never pertinent to the issue of patent invalidity, because such opinions would necessarily be legal opinions, that theory is mistaken. Instead, experts can testify, and in some cases may be required to testify, to provide factual background necessary for determining patent invalidity.

HemCon cites no specific statement in Dr. Langer’s declaration as merely a legal conclusion. Instead, HemCon’s criticisms of Dr. Langer’s declaration relate to the substance of the opinions. HemCon disagrees with Dr. Langer’s opinions and argues that Dr. Langer’s analysis is flawed. As presented, those arguments do not provide a basis for striking the declaration or any part of it.

II. Marine Polymer's Motion to Strike Portions of the Declaration of Paul A. Sandford

HemCon filed the declaration of Paul A. Sandford, Ph.D., to support its motion for summary judgment. Dr. Sandford is a fact witness, not an expert witness.³ Marine Polymer moves to strike paragraphs 8 through 13 of Dr. Sandford's declaration on the ground that those paragraphs are expert opinion testimony, which cannot be offered by a lay witness.

A. Nature of the Testimony

Fact witnesses testify to concrete facts based on their personal observations and perceptions. See United States v. Freeman, 498 F.3d 893, 904-05 (9th Cir. 2007). An affidavit or declaration must be based on the witness's personal knowledge, and statements as to the witness's information or belief do not satisfy Rule 56(e). Perez v. Volvo Car Corp., 247 F.3d 303, 315 (1st cir. 2001). A fact witness may also give lay opinions or inferences "which are (a) rationally based on the perception of the witness, (b) helpful to a clear understanding of the witness'

³The deadline for disclosing expert witnesses was March 23, 2007. HemCon does not contend that Dr. Sandford would testify as an expert witness.

testimony or the determination of a fact in issue, and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701. In contrast, expert witnesses must be qualified as such and then, "[i]f scientific, technical, or other specialized knowledge will assist the trial of fact to understand the evidence or determine a fact in issue," an expert witness may give an opinion that satisfies the requirements of an adequate factual basis, reliable principles and methods, and reliable application of the principles and methods. Fed. R. Evid. 702. Nevertheless, a witness may testify about facts he observed even though he also happens to be an expert in the area. Gomez v. Rivera Rodriguez, 344 F.3d 103, 113 (1st Cir. 2003).

"The line between expert testimony under Fed. R. Evid. 702 and lay opinion under Fed. R. Evid. 701 is not easy to draw." United States v. Ayala-Pizarro, 407 F.3d 25, 28 (1st Cir. 2005) (internal quotation marks omitted). Lay opinions under Rule 701 are based on the witness's personal experience, often derived from the witness's job. United States v. Santiago, --- F.3d ---, 2009 WL 709419, at *3 (1st Cir. Mar. 19, 2009). All experience-based opinions, however, are not admissible under Rule 701. United States v. Page, 521 F.3d 101, 105 (1st Cir. 2008). Rule 701 was amended in 2000, adding the requirement that a lay

opinion not be based on scientific, technical, or other specialized knowledge required under Rule 702, to avoid allowing parties to dress an expert witness "in lay witness clothing." Fed. R. Evid. 701 (advisory committee notes).

Despite the 2000 amendments, witnesses have been permitted to testify under Rule 701 based on their specialized knowledge of the business in which the witness is employed. See United States v. Munoz-Franco, 487 F.3d 25, 35 (1st Cir. 2007); Hynix Semiconductor Inc. v. Rambus Inc., 2008 WL 504098, at *4 (N.D. Cal. Feb. 19, 2008). A witness's testimony about the obviousness of an invention, in patent litigation, however, requires "highly technical and specialized knowledge" that is beyond the scope of Rule 701. Freedom Wireless, Inc. v. Boston Comms. Group, Inc., 369 F. Supp. 2d 155, 157 (D. Mass. 2005). Other district courts, including this court, have not allowed lay witness opinion testimony on technical matters involving patent litigation. See Hynix Semiconductor, 2008 WL 504098, at *4 n.3 (citing cases); Insight Tech., Inc. v. SureFire, LLC, 2007 WL 3244092, at *2 (D.N.H. Nov. 1, 2007) (authentication of animations used in patent litigation beyond the scope of Rule 701 testimony).

In addition, issues pertaining to patent validity and infringement "are analyzed in great part from the perspective of a person of ordinary skill in the art, and testimony explaining

the technical evidence from that perspective may be of great utility to the factfinder.” Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1361 (Fed. Cir. 2008). One who is not qualified as one skilled in the art cannot assist the trier of fact to determine a fact in issue with respect to patent validity or infringement. Id. at 1362. “Admitting testimony from [a witness] with no skill in the pertinent art, serves only to cause mischief and confuse the factfinder.” Id.

In paragraphs 8 through 11, Dr. Sandford describes his observations made during visits to HemCon’s manufacturing facility and Primex’s chitosan manufacturing facility in July and August of 2008. Marine Polymer objects to Dr. Sandford’s conclusions at the end of paragraph 8 and in paragraphs 9 through 11 that the process he observed at Primex for manufacturing chitosan did not have material differences from the process he described in his 1989 article, “Chitosan: Commercial Uses and Potential Applications.” In paragraphs 12 and 13, Marine Polymer objects that Dr. Sandford offers opinions about the teachings of another patent (“Malette patent”), about Malette’s 1983 article on chitosan, about the teachings of Marine Polymer’s ‘245 patent, and about a comparison of the ‘245 patent with Primex’s manufacturing processes.

HemCon contends that Dr. Sandford's declaration does not offer opinions. HemCon notes the carefully chosen language that does not explicitly state opinions or conclusions on the issues of patent validity or infringement. HemCon also asserts that any opinions are allowable under Rule 701.

1. Paragraph 8

In paragraph 8, Dr. Sandford states that he inspected HemCon's manufacturing facility on July 24, 2008, and that he saw chitosan supplied by Primex being used as an ingredient for HemCon's bandage products. He states that HemCon dissolved chitosan and filtered it as Dr. Sandford had described in his 1989 article. In conclusion, Dr. Sandford states:

The manufacturing steps of (1) dissolving the chitosan in a solution of acetic acid and then (2) drying the solution to leave a chitosonium acid salt are specifically disclosed at page 56 of my 1989 Article I saw no other steps taken that would have resulted in improved purity of the chitosan used by HemCon other than those disclosed in my 1989 Article."

Dec. ¶ 8. In that part of his declaration, Dr. Sandford offers his opinion that HemCon's manufacturing process does not include any additional steps not disclosed in his article to improve the purity of the chitosan used in HemCon's products. His opinion is based on his single visit to HemCon's manufacturing facility. As

such, Dr. Sandford's opinion is based on his scientific, technical, or other specialized knowledge of the chitosan manufacturing process, other than knowledge of his own business, which falls outside of Rule 701. Therefore, his challenged statements are opinions that are not admissible under Rule 701.

2. Paragraph 9

Dr. Sandford states that he visited the Primex manufacturing facility on August 13, 2008, where he observed Primex's methods for manufacturing the chitosan which is used in HemCon's products. Some of the information he recounts does not appear to be based on his personal observations. Specifically, he explains that the amount of deacetylation needed determines the temperature of the reactor and the time needed for the process, and that the plant manager explained the washing and packaging process. That part of his declaration is not based on his personal knowledge and is excluded.

3. Paragraphs 10 and 11

Paragraphs 10 and 11 present Dr. Sandford's opinion that Primex's manufacturing process is the same as or not materially different from the process described in his 1989 article. As is the case with his opinion in Paragraph 8, Dr. Sandford's opinions

require scientific, technical, or other specialized knowledge, which is not derived from his own business, making the opinions fall outside of Rule 701. Therefore, the opinions stated in paragraphs 10 and 11 are not admissible as facts based on personal knowledge or as opinions under Rule 701.

4. First Occurrence of Paragraphs 12 and 13

In paragraph 12, Dr. Sandford discusses his review of U.S. Patent 4,394,373 to Malette, explaining what the patent would teach a person of ordinary skill in the art. In paragraph 13, Dr. Sandford states that Malette's article on chitosan informed him "that chitosan made from shrimp shells is non-toxic in animals and that it can safely be used as a hemostatic without adverse affect [sic]." Both paragraphs 12 and 13 express Dr. Sandford's opinions, which are based on scientific, technical, or other specialized knowledge. Therefore, neither is a lay opinion admissible under Rule 701.

5. Second Occurrence of Paragraphs 12 and 13

Dr. Sandford offers his "understanding" based on his "knowledge as a person of ordinary skill in the art" in paragraph 12 about the teachings of Marine Polymer's '245 patent. Among other "understandings" Dr. Sandford expresses, he states "no

procedure applicable to the isolation, purification, and concentration of chitin or chitosan from animal crustacean sources, such as shrimp shells, is disclosed." He also states that he "believe[s] that [the '245 patent] does not provide any information that would enable me or any other person of ordinary skill in the art to perform the isolation, purification, and concentration of chitin and chitosan from animal crustacean sources, such as shrimp shells." Dr. Sandford set forth additional opinions based on his knowledge as one skilled in the art and on his belief about what one skilled in the art would learn from the '245 patent. Dr. Sandford elaborated on his opinions with specific comments about different parts of the '245 patent.

In paragraph 13, Dr. Sandford states:

Based upon my personal knowledge as a person of ordinary skill in the art, and after my review of U.S. Patent 6,864,245, I believe as a person of ordinary skill in the art that Primex's method of manufacture of chitin and method of converting chitin into the chitosan supplied to HemCon that I personally observed bear no similarity to the procedure for the isolation, purification, and concentration of either chitin or chitosan described in U.S. Patent 6,864,245.

Dr. Sandford supports his initial opinion with additional observations based on his knowledge as one skilled in the art. Dr. Sandford concludes by stating, that "as a person of ordinary skill in the art, I believe no steps taken by HemCon in the

manufacture of the HemCon® Bandage result in improved purity of the chitosan it purchases from Primex."

All of Dr. Sandford's opinions expressed in paragraphs 12 and 13 are based on expertise that is outside the scope of Rule 701. In addition, to the extent his statements are based on his belief about something, such statements are not based on personal knowledge, as required by Rule 56(e), and are not competent to support or oppose summary judgment.

B. Exclusion

Marine Polymer contends that Dr. Sandford's expert opinions must be excluded because he was not disclosed as an expert witness. HemCon primarily argues that Dr. Sandford does not offer expert opinions. In passing, however, HemCon also asserts that Dr. Sandford's declaration was substantially justified and that Marine Polymer was not prejudiced by its late disclosure.

Federal Rule of Civil Procedure 37(c)(1) provides that "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion . . . unless the failure was substantially justified or is harmless." Federal Rule of Civil Procedure 26(a)(2) requires parties to disclose to other parties any witness that may be used at trial

to provide expert testimony. The deadline for disclosure under Rule 26(a)(2) in this case was March 23, 2007.

It is undisputed that HemCon failed to disclose Dr. Sandford as an expert witness under Rule 26(a)(2). Indeed, HemCon has not now complied with the requirements of Rule 26(a)(2). In deciding whether to exclude expert testimony under Rule 37(c)(1), the court considers the history of the litigation, the party's need for the expert testimony, the party's justification for late disclosure, and any prejudice to the opposing party caused by the late disclosure. Santiago-Diaz v. Lab. Clinico Y De Referencia Del Este & Sara Lopez, M.D., 456 F.3d 272, 276 (1st Cir. 2006). The party offering undisclosed evidence bears the burden of showing substantial justification or that the failure was harmless. Primus v. United States, 389 F.3d 231, 234 (1st Cir. 2004).

HemCon offers no justification for failing to disclose Dr. Sandford as an expert witness. Instead, HemCon asserts that its failure to disclose "is not unfairly prejudicial" to Marine Polymer because Dr. Sandford was deposed. HemCon admits, however, that even if Marine Polymer had asked Dr. Sandford at his deposition about HemCon's and Primex's manufacturing processes, which are the subject matter of his present declaration, he would not have been able to answer the questions

because he had not visited the manufacturing facilities at the time of the deposition. HemCon also faults Marine Polymer for not requesting a continuance under Federal Rule of Civil Procedure 56(f) to take another deposition of Dr. Sandford.

HemCon bears the burden of showing substantial justification or that its nondisclosure is harmless. It has failed to carry its burden. Therefore, the expert opinion testimony included in Dr. Sandford's declaration is struck.

Conclusion

For the foregoing reasons, the defendant's motions to strike (documents no. 85 and 102) are denied. The plaintiff's motion to strike (document no. 87) is granted to the extent that the following parts of Paul A. Sandford's declaration are struck:

Paragraph 8: Third, sixth, seventh, and eighth sentences.

Paragraph 9: Ninth and tenth sentences.

Paragraph 10: Entire paragraph.

Paragraph 11: Entire paragraph.

1st Paragraph 12: Entire paragraph.

1st Paragraph 13: Entire paragraph.

2d Paragraph 12: Entire statement including subsequent paragraphs.

2d Paragraph 13: Entire paragraph.

SO ORDERED.


Joseph A. DiClerico, Jr.
United States District Judge

March 24, 2009

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